CHAPTER IV

CONCLUSION

1. The paracetamol elixir, Brand E , and the paracetamol suspensions ,Brand S1, Brand S2, Brand S3 and Brand S4, met the B.P.1980 and the U.S.P.XXI(1985), respectively, for requirements of the content of active ingredient.

2. The in vitro absorption rate constants in both artificial gastric and intestinal conditions, predicted from the Sartorius Absorption Simulator SM16750 were analyzed. Results indicated that the passive diffusion and absorption of paracetamol from suspensions were not statistically significant differences between the original Brand S1 and the Brand S2 or Brand S4 ($p>0.05$). Also, the in vitro absorption rate constants from the elixir and suspensions were not statistically significant difference ($p>0.05$).

3. The diffusion rate , Kd, and the in vitro absorption rate constants , Ki, were higher in simulated intestinal condition than those in simulated gastric condition.

4. The relative bioavailability of four commercial brands of paracetamol suspensions to paracetamol elixir were studied in eight normal subjects using urine data. The urinary excretion rate profiles were well described by a one-compartment open model with first order absorption and first order elimination. Data were analyzed using CSTRIP computer program. Results indicated that the original brand of paracetamol suspension (Brand S1) and the other brands were bioequivalent with respect to $[Du]_{\infty}$, (dDu/dt)max, t_{∞} and Ka. Also, it was worthy to note that the paracetamol suspension and that elixir dosage form were bioequivalent. The relative bioavailability of paracetamol suspensions with respect to paracetamol elixir (Brand E) were 104.31, 98.35, 104.12 and 106.74 % for Brands S1, S2, S3 and S4,respectively.

5. In this study, the maximum amount of paracetamol excreted into the urine within 32 hours was about 70-75 % of the administered dose, 600 mg.

6. For Thai healthy volunteers, the overall elimination rate constant (K) of paracetamol was 0.1615 hr^{-1} (0.1591-0.1679 hr^{-1}) and the half-life of paracetamol was 4.32 hours (4.14-4.43 hours).

7. An attempt to correlate the in vitro absorption rate constants (Ki) and the in vivo absorption rate constants (Ka) was made. Results indicated that these values

were not related. This is possibly due to the instrument used in in vitro study is not appropriate with suspensions.

8. With respect to paracetamol elixir, one can evaluate and select the paracetamol suspension in order to provide more safety for children and equivalently therapeutic effects.

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